## 510(k) Summary

AUG 2 2 2012

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| **Submitter:** | Edwards Lifesciences LLC |
| **Contact Person:** | Spencer Walker, Regulatory Affairs Associate III<br>12050 Lone Peak Pkwy<br>Draper, UT 84020<br>(801) 565-6100 |
| **Date Prepared:** | August 17, 2012 |
| **Trade Name:** | Edwards Percutaneous Sheath Introducer |
| **Classification Name:** | Catheter Introducer<br>21 CFR Part 870.1340, Product Code DYB, Class II |
| **Predicate Device:** | K981909: Baxter Hemostasis Valve Introducer |

**Device Description:**

The triple lumen percutaneous sheath introducer is used to access the venous system and to facilitate catheter insertion. The multi-lumen feature of the Introducer also allows access to the venous system for administration of fluids, blood sampling and for pressure monitoring through the additional lumens. The introducer is recommended to facilitate insertion of 7.5 – 8.5 French devices.

The introducer is composed of a valve housing to which a sheath is attached distally and three side arm/extension tubes are connected proximally. The valves located in the housing body provide a seal around a catheter when inserted through the introducer and prevent backflow when no catheter is present. A dilator is provided with the introducer to ease insertion of the device into the vessel.

The devices are provided sterile and non-pyrogenic; they are intended for single use only.

**Indications For Use:**

The Edwards Percutaneous Sheath Introducer is indicated for use in patients requiring access of the venous system and to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter).

**Intended Use**

The Edwards Percutaneous Sheath Introducer is intended to be used to access the venous system and to facilitate catheter insertion. The Percutaneous Sheath Introducers allow access to the venous system for administration of fluids, blood sampling and for pressure monitoring through the additional lumens.

**Comparative Analysis:**

The Introducer is substantially equivalent to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance. The introducer has been fully assessed within the Edwards' Risk Management and Design Controls systems.

**Functional/Safety Testing:**

The following functional tests were performed. All data met pre-determined acceptance criteria.

- Biocompatibility – Per ISO 10993-1 for External communicating device, direct circulating blood path, duration ≥ 24 hours.
- Tensile testing – Force required to remove mechanical locks or bonded assembly parts.
- Insertion and Retraction Force Tests – Insertion and retraction force of a catheter through the entire introducer sheath.
- Introducer Valve Leak testing – Inspection of pressure drop of the introducer valve with and without a catheter present.
- Infusion Pressure –Device's ability to administer fluids through the introducer ports with a catheter in place.
- Catheter Compatibility – Ensure catheter passes freely through the introducer valve while maintaining catheter functionality.

All data met acceptance criteria.

**Conclusion:**

The Edwards Percutaneous Sheath Introducer is substantially equivalent to the cited predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 2 2 2012

Edwards Lifesciences, LLC
c/o Mr. Spencer Walker
Regulatory Affairs Associate III
12050 Lone Peak Pkwy
Draper, UT 84020

Re: K121185
Trade Name: Percutaneous Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II (two)
Product Code: DYB
Dated: August 2, 2012
Received: August 3, 2012

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

# Statement of Indications for Use

## Indications for Use

510(k) Number (if known): K121185

Device Name: Edwards Lifesciences Percutaneous Sheath Introducer

The Edwards Percutaneous Sheath Introducer is indicated for use in patients requiring access of the venous system and to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter).

Prescription Use x OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121185